

510(k) Summary**TelZuit Cardiac Monitoring System****1. SPONSOR**

TelZuit Technologies, Inc.
7044 Stapoint Court
Winter Park, FL 32792

Contact Person: Don Sproat, 407-657-0128
Date Prepared: April 17, 2003

2. DEVICE NAME

Proprietary Name: TelZuit Cardiac Monitoring System
Common/Usual Name: Ambulatory electrocardiograph recorder and transmitter
Classification Name: Telephone electrocardiograph (ECG) transmitter and receiver

3. PREDICATE DEVICES

- CardioNet Ambulatory ECG Monitor, CardioNet, Inc. (K003707)
- CardioBeeper® CB-12L, Meridian Medical Technology (K965101)

4. INTENDED USE

The TelZuit Cardiac Monitoring System consists of a 4-channel ECG (electrocardiograph) monitor (TelZuit Electrode Array Patch) and the TelZuit Cardiac Monitoring Recorder. The TelZuit Cardiac Monitoring Recorder stores and transmits data received from the TelZuit Electrode Array Patch via telephone to a remotely located ECG analysis station for evaluation by a medical professional.

5. DEVICE DESCRIPTION

The TelZuit Cardiac Monitoring System is a transtelephonic ambulatory ECG recorder consisting of the TelZuit Electrode Array Patch and TelZuit Cardiac Monitoring Recorder. These components, when used together, allow a patient to

collect and transmit their ECG data to an analysis station for evaluation by a medical professional.

The TelZuit Electrode Array Patch is a multi-layer patch containing four embedded ECG electrodes and leads and a transmitter mounted on a Mylar substrate that is affixed to the patient's chest for monitoring ECG activity. Two models, Models A and B, are available that differ in lead placement and configuration. The electrode configuration in the TelZuit Electrode Array Patch Model A corresponds to positions of Lead I, Lead II, Lead III, and V2 for use with 12 Lead Algorithms. The electrodes in the TelZuit Electrode Array Patch Model B are positioned orthogonally so that the leads correspond to positions of EASI & G for use with Modified Frank Algorithms.

Each TelZuit Electrode Array Patch model is supplied in different sizes with lengths of 8.0, 8.5, 9.0, and 9.5 inches (203, 216, 229, 241 mm). The electrodes incorporated in all versions of the TelZuit Electrode Array Patch are identical to electrodes cleared for marketing by Bristol Medical Electronics, Inc., (K841944) and comply with ANSI/AAMI EC 12, "Disposable ECG Electrodes."

The TelZuit Cardiac Monitoring Recorder captures and stores digitized ECG data transmitted from the TelZuit Electrode Array Patch, and transmits this information to a remotely located receiving and analysis station via a modified Samsung Portable Dualband Tri-Mode personal digital assistant (PDA) with cellular telephone capabilities. The device has a touchscreen LCD display. Recording and transmission of ECG data occurs continuously while the TelZuit Electrode Array Patch and TelZuit Cardiac Monitoring Recorder are active. The patient may also record a cardiac event via the LCD display screen on the TelZuit Cardiac Monitoring Recorder. The TelZuit Cardiac Monitoring Recorder also continuously monitors the operational status of the TelZuit Cardiac Monitoring System and informs the user if an error is detected.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The proposed TelZuit Cardiac Monitoring System and the CardioNet Ambulatory ECG Monitor and CardioBeeper® CB-12L predicate devices are all intended to be used to collect a patient's ECG information and transmit the information via telephone to a remotely located ECG analysis station for evaluation by a medical professional. The design of the proposed and predicate devices allows a patient to collect and transmit their ECG information without direct physician supervision.

Like the proposed TelZuit Cardiac Monitoring System, the predicate CardioNet Ambulatory ECG Monitor and CardioBeeper® CB-12L include patient-worn electrodes and sensors to record patient ECG information and devices designed to receive ECG information from the sensor and then transfer the information to an ECG analysis station. The major differences include:

- Means by which the ECG sensors are positioned (fixed array or individual placement)
- Mode of ECG signal transmission (continuous, event-initiated, or both)
- Length of ECG recording

The proposed TelZuit Cardiac Monitoring System complies with recognized industry standards for ambulatory ECG electrocardiograph devices. Performance testing demonstrates that ECG tracings can be accurately and reliably reproduced from the signals transmitted by the TelZuit Cardiac Monitoring System. Therefore, the technical differences between the proposed and predicate devices do not raise new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 2003

TelZuit Technologies, Inc.
c/o Cynthia J.M. Nolte, Ph.D., RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K031229

Trade Name: TelZuit Cardiac Monitoring System

Regulation Number: 21 CFR 870.2920

Regulation Name: Telephone Electrocardiograph Transmitters and Receivers

Regulatory Class: Class II (two)

Product Code: DXH

Dated: April 17, 2003

Received: April 18, 2003

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

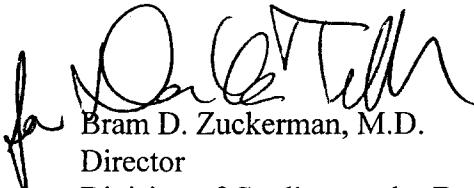
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: TelZuit Cardiac Monitoring System

Indications for Use:

The TelZuit Cardiac Monitoring System consists of a 4-channel ECG (electrocardiograph) monitor (TelZuit Electrode Array Patch) and the TelZuit Cardiac Monitoring Recorder. The TelZuit Cardiac Monitoring Recorder stores and transmits data received from the TelZuit Electrode Array Patch via cellular telephone to a remotely located ECG analysis station for evaluation by a medical professional.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K031229

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)